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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 1291.1121109							
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p style="text-align: center;">E-FILED on January 6, 2009</p> <p>Signature <u><i>Kathleen L. Bookley</i></u></p> <p>Typed or printed name <u>Kathleen L. Bookley</u></p>		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">Application Number 10/685,761</td> <td style="width: 50%; padding: 2px;">Filed October 15, 2003</td> </tr> <tr> <td colspan="2" style="padding: 2px;">First Named Inventor Thomas W. Davison</td> </tr> <tr> <td style="padding: 2px;">Art Unit 3734</td> <td style="padding: 2px;">Examiner Vi. X. Nguyen</td> </tr> </table>		Application Number 10/685,761	Filed October 15, 2003	First Named Inventor Thomas W. Davison		Art Unit 3734	Examiner Vi. X. Nguyen
Application Number 10/685,761	Filed October 15, 2003								
First Named Inventor Thomas W. Davison									
Art Unit 3734	Examiner Vi. X. Nguyen								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 20px;"> <div style="width: 45%;"> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>40,364</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> </div> <div style="width: 50%; text-align: right;"> <p><u><i>Nancy J. Parsons</i></u> Signature</p> <p>Nancy J. Parsons Typed or printed name</p> <p><u>612-677-9050</u> Telephone number</p> <p><u>January 6, 2009</u> Date</p> </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>									
<p><input type="checkbox"/> *Total of _____ forms are submitted.</p>									

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Thomas W. DAVISON et al.	Confirmation No.:	6309
Serial No.:	10/685,761	Examiner:	Vi X. Nguyen
Filed:	October 15, 2003	Group Art Unit:	3734
Docket No.:	1291.1121109	Customer No.:	33469
Title:	CANNULA FOR RECEIVING SURGICAL INSTRUMENTS		

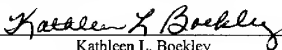
PRE-APPEAL CONFERENCE BRIEF

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By



Kathleen L. Bockley

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 71-76, 79-81, and 83 remain rejected under 35 U.S.C. §102(b) as being anticipated Mollenauer et al. (U.S. Patent No. 5,634,937). This rejection is respectfully traversed. In the previous response, Applicants argued that independent claims 71 and 80 each recite, "wherein the retractor is structured to remain in the expanded configuration when the expander is withdrawn from the access path", and that Mollenauer et al. do not appear to teach such a structure. The Examiner responded by asserting that this limitation is intended use and is not deemed to impose any structural limitations on the claims distinguishable over Mollenauer, which is capable of being used as claimed if one desires to do so. Applicants respectfully disagree and submit the claim language does provide additional structure.

One of ordinary skill in the art would understand that a device "structured to remain in the expanded configuration when the expander is withdrawn from the access path" would indeed have a structure to enable the device to perform as recited. Mollenauer et al. teach

The distal or bottom portion 16 of the threaded skin seal may have a straight or cylindrical bore to provide a tight fit with cannulas that have an outer diameter matching the inner diameter of this straight bore.

See column 5, lines 52-56. Mollenauer et al. also specifically teach:

Because the balloon is pliable and conforms around any device within the skin seal, the graspers may be manipulated inside the cannula without breaking the insufflation seal. As the graspers 7 are manipulated, the membrane conforms around graspers but yields to allow the graspers to be opened, closed, twisted, pushed and pulled within the skin seal without substantially degrading the seal created by the membrane. It should be noted that a perfectly airtight seal is not necessary, and some leakage of insufflation gas or fluid is acceptable, so long as insufflation gas or fluid can be injected at a rate sufficient to make up for any losses. Where the cannula itself is made of a soft pliant material such as latex rubber or silicone rubber, the forceps may be manipulated even further, and deformation of the skin seal 28 will permit a wider range of motion for the forceps. Skin seal 28 is shown with a pair of conventional surgical scissors 31 or shears disposed through the skin seal. The scissors may be opened wide, as shown, and the distal or proximal end of the skin seal will yield and flare out to allow operation of the scissors through their full range of motion and opened through the full throw (the "throw" referring to the length of arc 35 over which the graspers or scissors may be opened) of scissors 31 or graspers, as illustrated by flared distal portion 36 of skin seal 28.

See column 7, line 65 through column 8, line 21 and FIG. 8. Mollenauer et al. appear to teach a skin seal structure to conform to the instrument inserted therethrough in order to maintain a seal. The skin seal thus appears to be structured to expand when an instrument such as scissors are opened or expanded, and to contract around the scissors when they are closed. This structure appears to be necessary to achieve the purpose of Mollenauer et al., which appears to be maintaining the seal around the scissors.

Based on the Examiner's assertion that the device of Mollenauer et al. is capable of being used as claimed if one desires to do so, it appears the Examiner has misinterpreted the reference. Applicants submit that one of ordinary skill in the art would not interpret the skin seal of Mollenauer et al. to be structured such that it was capable of remaining in the expanded configuration when the expander is withdrawn from the access path, as asserted by the Examiner. Mollenauer et al. appears to teach the opposite structure, where the skin seal contracts around the closed scissors in order to maintain the desired seal. Mollenauer et al. appear to teach a skin sleeve structured for insufflation, in which the sleeve provides a seal between a skin incision and instruments used in abdominal surgery when pressurized gas is injected into the abdomen to assist in the surgical procedure. See column 1, lines 54-67.

Mollenauer et al. appear to teach a soft, flexible skin seal 28 that expands and contracts to allow for movement of scissors 31. In order for the skin seal to function and maintain the desired sealing effect, the skin seal 28 would be expected to contract to a closed position when the scissors 31 are removed. The Examiner appears to be considering the scissors 31 as the claimed expander. However, the structure of the soft, pliant skin seal 28 taught by Mollenauer et al. does not appear to be structure to remain in an expanded configuration when the scissors are withdrawn. In fact, as shown by the above teaching, Mollenauer et al. appear to teach the opposite structure as that recited in the claims. Mollenauer et al. thus do not appear to teach the claimed structure. As such, the rejection is in error.

In the Response to Arguments section on page 4 of the final Office Action, the Examiner asserts that “[s]ince the structure of Mollenauer meets all the structure elements of claims 71 and 80, Mollenauer anticipates the claims. There are no structure limitations of the Mollenauer device that would prevent it from being used in the spinal access system if one chooses to do so.” As discussed above, Mollenauer fails to teach a device structured to remain in the expanded configuration when the expander is withdrawn from the access path, as asserted by the Examiner. In fact, Mollenauer appears to teach the opposite structure: a skin seal structured to seal around devices inserted therethrough and return to a sealed state upon removal of instruments, to achieve the intended purpose of providing a skin seal.

Additionally, if the Examiner is considering the specific retractor structure recited in the claims to be inherent in Mollenauer et al., Applicants submit that there is no basis for such an interpretation. MPEP 2112 IV. states:

“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Applicants submit that the claimed structure, in particular the retractor structured to remain in the expanded configuration when the expander is withdrawn from the access path, is not necessarily present in Mollenauer et al. It appears the Examiner is

asserting that the structure of Mollenauer et al. could be modified to achieve the claimed structure, which is not a proper basis for an anticipation rejection.

Further, Mollenauer et al. appears to provide a direct teach away from the claimed structure. Because Mollenauer et al. teaches a skin seal structured to provide a seal around scissors when they are opened and closed, it would appear that modifying the skin seal of Mollenauer et al. to remain in the expanded configuration when the scissors are withdrawn would destroy the functionality of the skin seal. The only motivation for one of ordinary skill in the art to make such a modification is found in the instant specification, which is not a proper basis for obviousness. Such an argument would be in error.

MPEP § 2131 recites:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

For at least the reasons set forth above, Mollenauer et al. fail to teach the identical structure recited in independent claims 71 and 80 and the claims dependent thereon. The rejection is thus in error.

Claim 82 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Mollenauer et al. (U.S. Patent No. 5,634,937) in view Nwawka (U.S. Patent No. 6,036,638). This rejection is respectfully traversed. For at least the reasons set forth above, Mollenauer et al. fail to teach the elements of independent claim 80, from which claim 82 depends. Nwawka does not appear to teach or suggest what Mollenauer et al. lacks, thus even if one were to combine the teachings, one would not arrive at the system as claimed.

Additionally, the Examiner states as a reason for modifying Mollenauer et al. with Nwawka, "because one of ordinary skill in the art would have been able to carry out such a substitution, and the results were reasonably predictable." Applicants submit that this is not a proper basis for obviousness. MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless **>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").<

Further, it is unclear how one would modify the skin seal of Mollenauer et al. to move along a slot as taught by Nwawka to lead to a pivot mechanism. Mollenauer et al. appear to rely on a soft, pliant, one piece design for the skin seal to provide the desired sealing properties. Thus, attempting to modify Mollenauer et al. to include a guide and slot would not provide predictable results. There is no motivation for combining the references, thus the rejection is in error.

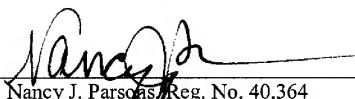
If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Thomas W. Davison et al.

By their attorney,

Date: 1/9/09


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